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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,458	02/11/2000	Michael R. Rosen	61020-A/HOW/PJP	6325

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/05/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,458

Applicant(s)

ROSEN ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004 (Amendment and RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 2/17/04 has been entered.

Claim Rejections - 35 USC § 102

2. Claims 1, 9-11, 20, 28-30, 39 and 47-49 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ben-Haim et al. (US 6363279).

Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field (col. 1 @ 31-45) to modify/ alter/ remodel the action potentials, the ionic pumps and the channels of the heart (col. 2 @ 6 – col. 3 @ 32), hence preventing arrhythmias such as ventricular fibrillation (col. 8 @ 41-48).

The channels that connect the heart, read to include gap junction channels, are modified/ remodeled by electrical stimulation (col. 2 @ 6 – col. 3 @ 32; col. 27 @ 12-27 and 52-57; col. 31 @ 1-5). While the gap junction channels are not specifically mentioned when Ben-Haim addresses the channels of the heart, it is inherent that the Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the record by Winslow et al. (US 5947899) (col. 5 @ 28 – col. 6 @ 3; col. 6 @ 33-53).

Refractory periods are modified by electrical stimulation (col. 8 @ 3-5; col. 47 @ 37-45; col. 8 @ 66 – col. 9 @ 3; col. 9 @ 15-19; col. 17 @ 26-35; col. 17 @ 45-46; col. 31 @ 26-31).

Ion channels are modified by electrical stimulation (col. 26 @ 62 – col. 27 @ 27; col. 27 @ 43-57; col. 31 @ 1-5).

Mechanical and electrical changes in the heart occur over time as the heart is altered/ remodeled (col. 9 @ 51-55; col. 38 @ 48 – col. 39 @ 10). Electrodes can be attached by sewing (col. 30 @ 9-12). Electrodes can be placed in the heart or in vessels (col. 37 @ 30-35; col. 40 @ 48-51). Electrodes can be activated in pairs (col. 37 @ 15-17).

As to exciting the heart, resulting in remodeling of gap junctions, alter the effective refractory periods, or inducing ion channel remodeling, Ben-Haim et al. teach the heart is controlled/ altered/remodeled using electrical stimulation (col. 1 @ 26-27), hence modifying the action potentials, the ionic pumps and the channels of the heart (col. 2 @ 6 – col. 3 @ 32). As to gap junction channels, the channels that connect the heart are remodeled using electrical stimulation; the channels are read to include gap junction channels (col. 2 @ 6 – col. 3 @ 32; col. 27 @ 12-27 and 52-57; col. 31 @ 1-5). While the gap junction channels are not specifically mentioned when Ben-Haim addresses the channels of the heart, it is inherent that the Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the record by Winslow et al. (US 5947899) (col. 5 @ 28 – col. 6 @ 3; col. 6 @ 33-53). As to refractory periods, refractory periods are altered by electrical stimulation (col. 8 @ 3-5; col. 47 @ 37-45; col. 8 @ 66 – col. 9 @ 3;

col. 9 @ 15-19; col. 17 @ 26-35; col. 17 @ 45-46; col. 31 @ 26-31). As to ion channels, ion channels are remodeled by electrical stimulation (col. 26 @ 62 – col. 27 @ 27; col. 27 @ 43-57; col. 31 @ 1-5).

As to Ben-Haim et al. changing the muscle mass of the heart over time rather than remodeling the gap junction, altering the refractory period in the heart or inducing the ion channel remodeling, Ben-Haim et al. disclose methods to control and change the electrical and mechanic activity of the cardiac muscle cells that produce changes the muscle mass and changes in the action potential plateau duration, the activation time, the activation sequence, the contractability and the conduction pathways of the cardiac segment, hence Ben-Haim is read to remodel gap junctions, alter the heart refractory period and induce ion channel remodeling (col. 2 @ 6 – col. 3 @ 32; col. 7 @ 65-67; col. 34 @ 28-34).

As to Ben-Haim et al. only providing change and control of the cardiac processes in a current moment or until electrical stimulation ceases, Ben-Haim et al. apply stimulation to create cardiac process changes in the current moment. In addition, Ben-Haim et al. recognize applying electrical stimulation in the current moment produces long-term/ permanent changes of the cardiac processes, read as remodeling and altering of the cardiac processes. These long-term changes are reflected in a need for the therapy to be altered periodically and are reflected when treatment targets are met and the therapy is discontinued because the cardiac process has been changed to the point that therapy is no longer needed, hence Ben-Haim et al. disclose changes in the cardiac process in the moment and long-term (col. 9 @ 15-19; col. 9 @ 51 – col. 10 @ 3; col. 30 @ 34-37; col. 34 @ 15-38; col. 35 @ 55-59; col. 38 @ 48 – col. 39 @ 18).

The Applicant's Agents arguments filed 2/11/04 have been fully considered, but they are not convincing.

The Applicant's Agent asserts the Applicant's statements in the declaration submitted on 12/22/03 under 37 C.F.R. 1.132 were made to show that Ben-Haim et al. do not absolutely anticipate the instant invention. The Applicant's Agent asserts the Applicant's statements of "would not necessarily induce ion channel remodeling or remodel gap junctions", "would not necessarily result in inducing ion channel remodeling or remodeling of gap junctions", and "would not necessarily alter the relative refractory period" show that not all elements of the instant invention are taught by Ben Haim et al. in all cases. The Examiner does not find these statements convincing. As noted in the Advisory Action, Paper No. 27, the declaration filed 12/22/03 under 37 CFR 1.132 is insufficient to overcome the rejection of claims 1-60 based upon the references applied under 35 U.S.C 102(e) and 35 U.S.C. 103(a) as set forth in the last office action because the comments by the Applicant do not appear to have probative value, as the comments are not directed to evidence of unexpected results, commercial success, solution of long-felt but unsolved needs, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the Applicant. As detailed in the rejection of record, Ben-Haim et al. is read to apply non-excitatory electrical field that modifies the plateau currents and the force of contraction of the heart (applies an electrical stimulus to the heart that does excite it, resulting in altered activation) resulting in the remodelling of the gap junctions, altering of the effective refractory periods, and inducing ion channel remodeling, hence the rejection of record stands.

Claim Rejections - 35 USC § 103

3. Claims 2, 5, 12, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308).

As discussed in paragraph 2 of this action, Ben Haim et al. disclose the claimed invention except for the 7cm x 1 cm (claims 4, 23 and 42) strip (claims 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pairs are arranged in two columns (claims 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claims 5, 15, 24, 34, 43, 53 and 58-60).

Edwards et al. disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed to enable stimulation of electrode pairs (figure 7; col. 7 @ 38-52). Absent any teaching of criticality or unexpected results, it is understood the electrode can be configured as a 7cm x 1 cm strip with only two columns of electrodes. The configuration change is an obvious change in shape based on the specific application. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

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4. Claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (5681308) and further in view of Dahl et al. (US 5203348).

As discussed in paragraphs 2 and 3 of this action, modified Ben-Haim et al. disclose the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 17-18, 36-37 and 55-56), and
- the electrode connected to insulated stainless steel wire (claims 19, 38 and 57).

Dahl et al. disclose an electrode and teach that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (col. 5 @ 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor (col. 5 @ 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the materials of construction as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

5. Claims 7, 8, 26, 27, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348).

As discussed in paragraph 2 of this action, Ben-Haim et al. disclose the claimed invention except for the electrode being platinum or consisting essentially of unalloyed platinum.

Dahl et al. disclose an electrode and teach that it is known to fabricate an electrode with a platinum or platinum alloy conductor (col. 5 @ 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the platinum of platinum alloy conductor as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

6. Claims 6, 16, 25, 35, 44 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308) and further in view of Ideker (US 5873896).

As discussed in paragraphs 2 and 3 of this action, modified Ben-Haim et al. disclose the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at least 5 mm apart.

Idecker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (col. 3 @ 2-4). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al.,

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with the electrode spacing as taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythmias.

Statutory Basis

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

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5/2/04



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